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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CELLTRION, INC., CELLTRION HEALTHCARE CO., LTD., TEVA PHARMACEUTICALS USA, INC., AND TEVA PHARMACEUTICALS INTERNATIONAL GmbH,

Plaintiffs,

v.

GENENTECH, INC., BIOGEN INC., HOFFMANN-LA ROCHE INC., and CITY OF HOPE,

Defendants.

Case No. _____

COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT NON-INFRINGEMENT AND/OR INVALIDITY

REDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED

[CONFIDENTIAL PORTIONS REDACTED]

Plaintiffs Celltrion, Inc. ("Celltrion Inc."), Celltrion Healthcare, Co. Ltd. ("Celltrion Healthcare") (collectively "Celltrion"), Teva Pharmaceuticals International GmbH ("TPIG"), and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively "Teva") (collectively with Celltrion, Celltrion Healthcare, and TPIG, "Plaintiffs") bring this action for declaratory judgment of patent non-infringement and/or invalidity against Defendants Genentech, Inc. ("Genentech"), Biogen Inc. ("Biogen"), Hoffmann-La Roche Inc. ("Roche") and City of Hope. This is a case to protect Celltrion and Teva's efforts to bring more affordable drugs to market. Celltrion and Teva have developed technology to manufacture antibodies known to be effective in treating several types of cancer and other serious diseases, and have sought FDA approval to market a product containing these antibodies. Genentech has claimed that forty patents will be infringed by Celltrion and Teva. Rather than focusing their assertion, Defendants have rested on a complex series of patents from two dozen patent families. As Celltrion has already demonstrated to Genentech, these allegations are wrong and the panoply of vague allegations are simply intended to interfere with Celltrion and Teva's entry into the market. This case seeks to clear the underbrush of Defendants' allegations to ensure that Celltrion and Teva's biosimilar product can help millions of people facing life-threatening diseases today.

NATURE OF THE CASE

1. This is an action for declaratory judgment of non-infringement and/or invalidity relating to the following patents:

(i) U.S. Patent No. 6,331,415 ("the '415 patent");

(ii) U.S. Patent No. 6,417,335 ("the '335 patent");

(iii) U.S. Patent No. 6,455,043 ("the '043 patent");

(iv) U.S. Patent No. 6,489,447 ("the '447 patent");

(v) U.S. Patent No. 6,586,206 ("the '206 patent");

(vi) U.S. Patent No. 6,610,516 ("the '516 patent");

(vii) U.S. Patent No. 6,620,918 ("the '918 patent");

(viii) U.S. Patent No. 6,716,602 ("the '602 patent");

(ix) U.S. Patent No. 7,390,660 ("the '660 patent");

(x) U.S. Patent No. 7,485,704 ("the '704 patent");

(xi) U.S. Patent No. 7,682,612 ("the '612 patent");

(xii) U.S. Patent No. 7,807,799 ("the '799 patent");

(xiii) U.S. Patent No. 7,820,161 ("the '161 patent");

(xiv) U.S. Patent No. 7,923,221 ("the '221 patent");

(xv) U.S. Patent No. 7,976,838 ("the '838 patent");

(xvi) U.S. Patent No. 8,044,017 ("the '017 patent");

(xvii) U.S. Patent No. 8,206,711 ("the '711 patent");

(xviii) U.S. Patent No. 8,329,172 ("the '172 patent");

(xix) U.S. Patent No. 8,357,301 ("the '301 patent");

(xx) U.S. Patent No. 8,460,895 ("the '895 patent");

(xxi) U.S. Patent No. 8,512,983 ("the '983 patent");

(xxii) U.S. Patent No. 8,545,843 ("the '843 patent");

(xxiii) U.S. Patent No. 8,557,244 ("the '244 patent");

(xxiv) U.S. Patent No. 8,574,869 ("the '869 patent");

(xxv) U.S. Patent No. 8,633,302 ("the '302 patent");

(xxvi) U.S. Patent No. 8,710,196 ("the '196 patent");

(xxvii) U.S. Patent No. 8,771,988 ("the '988 patent");

(xxviii) U.S. Patent No. 8,821,873 ("the '873 patent");

(xxix) U.S. Patent No. 8,822,655 ("the '655 patent");

(xxx) U.S. Patent No. 9,047,438 ("the '438 patent");

(xxxi) U.S. Patent No. 9,080,183 ("the '183 patent");

(xxxii) U.S. Patent No. 9,296,821 ("the '821 patent");

(xxxiii) U.S. Patent No. 9,428,548 ("the '548 patent");

(xxxiv) U.S. Patent No. 9,428,766 ("the '766 patent");

(xxxv) U.S. Patent No. 9,487,809 ("the '809 patent");

(xxxvi) U.S. Patent No. 9,504,744 ("the '744 patent"); and

(xxxvii) U.S. Patent No. 9,714,293 ("the '293 patent") (collectively, "the patents-in-suit").

2. According to Genentech, the patents-in-suit relate to an antibody product called rituximab, which Genentech markets under the brand name Rituxan®. Rituxan® has been approved by the FDA for the treatment of several types of cancer, rheumatoid arthritis, and granulomatosis with polyangiitis and microscopic polyangiitis.

3. On information and belief, Genentech and Biogen[1] collaborated in the development of the technology underlying the patents-in-suit and collaborated on the development of Rituxan®. *See* https://www.biogen.com/en_us/therapies.html#partnered-therapies; https://www.roche.com/investors/updates/inv-update-2010-10-21b.htm. Rituxan® is jointly marketed in the United States by Genentech and Biogen.

4. On information and belief, Roche is an owner of certain patents-in-suit and has provided Genentech with the rights to enforce certain of the patents-in-suit.

5. On information and belief, each patent-in-suit is owned by at least one of Genentech, Biogen, Roche, or City of Hope.

6. A substantial controversy exists between Plaintiffs, on the one hand, and Genentech, Biogen, Roche, and City of Hope, on the other hand, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Celltrion Healthcare, Celltrion Inc., and TPIG entered into a business collaboration agreement to commercialize CT-P10, a biosimilar to Rituxan®. Celltrion Inc. submitted an Abbreviated Biologics License Application ("aBLA") to the FDA under 42 U.S.C. § 262(k) of the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") for licensure of a rituximab biological product (hereinafter, "biosimilar product," "CT-P10," or "Truxima®") that is highly similar to Rituxan®. Teva USA will sell and distribute the CT-P10 product in the United States. The FDA accepted Celltrion Inc.'s biosimilar application on June 27, 2017. Celltrion Inc. provided Genentech with a copy of its aBLA and other detailed information regarding the manufacturing processes used

[1] Biogen Inc. was previously known as Biogen Idec and IDEC Pharmaceuticals.

to make Truxima®, and in response, Genentech identified the patents-in-suit which Genentech alleges could reasonably be asserted against Plaintiffs if they were to manufacture, use, offer for sale, or sell in the United States, or import into the United States, the biosimilar product. Celltrion Inc. then provided Genentech with a detailed statement regarding the invalidity and/or non-infringement of the patents that Genentech identified, along with citations to the aBLA and other manufacturing information that Celltrion Inc. produced to Genentech to support such defenses. In response, Genentech provided Celltrion Inc. with a statement purporting to contain the factual and legal basis of Genentech's opinion that some of the patents-in-suit would be infringed by the commercial marketing of the biosimilar product.

7. Pursuant to 42 U.S.C. § 262(*l*)(8)(A), on [redacted], Celltrion Inc. provided Genentech with notice that the first commercial marketing of Truxima® will commence no earlier than 180 days from the date of the notice.

PARTIES

8. Celltrion Inc. is a corporation organized and existing under the laws of the Republic of Korea, with a principal place of business at 23 Academy-ro, Yeonsu-gu, Incheon, 406-840, South Korea.

9. Celltrion Healthcare, Co. Ltd. is a corporation organized under the laws of the Republic of Korea, having its principal place of business at 23 Academy-ro, Yeonsu-gu, Incheon, 406-840, South Korea.

10. Teva Pharmaceuticals USA, Inc. is a Delaware corporation with a principal place of business at 1090 Horsham Road, North Wales, PA 19454-1090.

11. TPIG is a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and principal place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland.

12. On information and belief, Defendant Genentech, Inc. is a corporation with its principal place of business in this District at 1 DNA Way, South San Francisco, CA 94080.

13. On information and belief, Defendant Biogen Inc. is a Delaware corporation with its principal place of business at 225 Binney St., Cambridge, MA 02142.

14. On information and belief, Defendant City of Hope is a not-for-profit organization organized and existing under the laws of California, having its principal place of business at 1500 East Duarte Road, Duarte, California 91010.

15. On information and belief, Defendant Hoffmann La-Roche Inc. is a company organized and existing under the laws of the State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424.

JURISDICTION AND VENUE

16. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

17. Celltrion Inc. provided to Genentech the aBLA required under 42 U.S.C. § 262(*l*)(2)(A), and also provided additional manufacturing information to Genentech. In response, Genentech identified the patents-in-suit pursuant to 42 U.S.C. § 262(*l*)(3)(A), which Genentech alleges could reasonably be asserted against Plaintiffs if they were to manufacture, use, offer for sale, or sell in the United States, or import into the United States, the biosimilar product. Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) explaining why Plaintiffs will not infringe any of the patents-in-suit. Genentech then provided Plaintiffs with a statement under 42 U.S.C. § 262(*l*)(3)(C) purporting to contain the factual and legal basis of Genentech's opinion that some of the patents-in-suit would be infringed by the commercial marketing of Celltrion's biosimilar product.

18. On [redacted], Celltrion provided notice of commercial marketing to Genentech pursuant to 42 U.S.C. § 262(*l*)(8)(A).

19. The Court has personal jurisdiction over Genentech because Genentech has its headquarters and principal place of business in the State of California, in this District. On

information and belief, Genentech's South San Francisco campus is its headquarters for its pharmaceutical operations in the United States. Genentech also maintains multiple other facilities in California, including a biotech manufacturing and clinical operations complex in Oceanside, California, and a biotechnology manufacturing plant in Vacaville, California.

20. Upon information and belief, Genentech markets, distributes and sells pharmaceutical products, including Rituxan®, in California, including in this District. Genentech's continuous and systematic corporate operations within California are so substantial and of such a nature to justify suit against it on causes of action arising from dealings entirely distinct from those activities.

21. The Court also has personal jurisdiction over Genentech because, among other reasons, Genentech's activities in California gave rise to this action. For example, Genentech, which is located in this District, directed its counsel in Los Angeles, California, to send Plaintiffs' counsel in this District (i) correspondence related to the BPCIA exchanges described above, (ii) a list of patents that it purports could reasonably be asserted against Plaintiffs, and (iii) a statement that purports to describe, among other things, the factual and legal basis of Genentech's opinion that patents that it owns, or for which it is an exclusive licensee, will be infringed by the commercial marketing of Plaintiffs' biosimilar product.

22. The Court has personal jurisdiction over Biogen because Biogen markets, distributes and sells pharmaceutical products, including Rituxan®, in California, including in this District. On information and belief, Biogen has collaborated with San-Francisco-based Genentech to develop the technology in the patents-in-suit and to develop and market Rituxan®. Biogen continues to jointly market Rituxan® with Genentech today. Rituxan® is a registered trademark of Biogen. Biogen also conducts, and recruits patients for enrollment in, clinical trials in this District. Biogen's continuous and systematic corporate operations within California are so substantial and of such a nature to justify suit against it on causes of action arising from dealings entirely distinct from those activities.

23. This Court also has personal jurisdiction over Biogen because Biogen has purposefully directed various activities at this District which gave rise to this action. For example, on information and belief, Biogen collaborated with South San Francisco-based Genentech regarding

the subject matter of certain patents-in-suit and/or entered into contractual agreements with Genentech regarding certain patents-in-suit. In addition, on information and belief, Biogen has knowingly consented to and/or collaborated with South San Francisco-based Genentech's enforcement actions regarding the patents-in-suit.

24. The Court has personal jurisdiction over City of Hope because, among other reasons, upon information and belief, it is organized under the laws of the State of California and has its principal place of business in California. Upon information and belief, City of Hope is the co-owner of one or more patents-in-suit. City of Hope also maintains a place of business for fundraising and development in the Northern District at 55 Hawthorne Street, Ste. 450, San Francisco, California 94105.

25. This Court also has personal jurisdiction over City of Hope because City of Hope has purposefully directed various activities at this District which gave rise to this action. For example, on information and belief, City of Hope collaborated with South San Francisco-based Genentech to research and/or develop the subject matter of certain patents-in-suit and/or entered into contractual agreements with Genentech regarding certain patents-in-suit. In addition, on information and belief, City of Hope has knowingly consented to and/or collaborated with South San Francisco-based Genentech's enforcement actions regarding one or more of the patents-in-suit.

26. The Court has personal jurisdiction over Roche because, upon information and belief, Roche researches, manufactures, and markets branded drug products, and continuously and systematically conducts business throughout the United States, including in California. Roche is licensed to do business in the State of California. Roche's headquarters for commercial operations are in this District at 1 DNA Way, South San Francisco, CA 94080. Roche's continuous and systematic corporate operations within California are so substantial and of such a nature to justify suit against it on causes of action arising from dealings entirely distinct from those activities.

27. This Court also has personal jurisdiction over Roche because Roche has purposefully directed various activities at this District which gave rise to this action. For example, on information and belief, Roche collaborated with South San Francisco-based Genentech to research and/or

develop the subject matter of certain patents-in-suit and/or entered into contractual agreements with South San Francisco-based Genentech regarding certain patents-in-suit. In addition, on information and belief, Roche has knowingly consented to and/or collaborated with Genentech's enforcement actions regarding one or more of the patents-in-suit.

28. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because, among other reasons, Genentech, Biogen, City of Hope, and Roche all reside and are subject to personal jurisdiction in this District for purposes of this action as set forth above. In addition, venue is proper in this district because a substantial part of the events that gave rise to this action occurred in this District. For example, on information and belief, one or more of Genentech, Biogen, City of Hope, and Roche collaborated in this District regarding the research and/or development of the subject matter of certain patents-in-suit and/or entered into contractual agreements with South San Francisco-based Genentech regarding certain patents-in-suit. In addition, on information and belief, one or more of Biogen, City of Hope, and Roche have knowingly consented to and/or collaborated with Genentech's enforcement actions regarding one or more of the patents-in-suit. Moreover, Genentech, which is located in this District, has directed certain activities at Plaintiffs' counsel in this District relating to the enforcement of the patents-in-suit, including the transmission of (i) correspondence related to the BPCIA exchanges described above, (ii) a list identifying the patents-in-suit among those patents that Genentech believes could reasonably be asserted against Plaintiffs following the submission of their subsection (k) application, and (iii) a statement that purports to describe Genentech's opinions regarding the infringement, validity, and enforceability of the patents-in-suit. Furthermore, Genentech, Biogen, Roche, and/or City of Hope have litigated in this District at least 19 separate actions relating to patents-in-suit, including those having civil action numbers 5-15-cv-01238; 3-13-cv-02045; 4-13-cv-00919; 3-13-cv-02904; 4-11-cv-02410; 3-11-cv-01925; 5-10-cv-04255; 5-10-cv-02037; 3-10-cv-00675; 3-09-cv-04919; 5-08-cv-05590; 3-08-cv-04909; 4-04-cv-05429; 3-04-cv-01910; 3-03-cv-01603; 3-01-cv-03560; 3:01-cv-00415; 5-01-cv-20434; 3-98-cv-03926.

FACTUAL BACKGROUND

29. Celltrion was founded in 2002 with the mission of developing and supplying medicines at an affordable cost to patients suffering from life-threatening and debilitating diseases. Such patients previously had limited access to advanced therapeutics such as biologic drugs due to their high cost and relative shortage of availability. Celltrion develops, manufactures, and distributes biosimilars and novel biologics to introduce competition in the pharmaceutical market for antibody biologics, to offer alternative solutions for previously limited, high-cost therapies. Because of their complexity, biologic drugs require substantially more effort, monetary resources and technical expertise to develop than traditional drugs that are synthesized chemically.

30. Over the last 15 years, Celltrion has made significant investments in human resources, facilities, and technology to become a global leader in biologics. Celltrion spear-headed global efforts to produce a biosimilar version of monoclonal antibody biologics, and received marketing approval for the world's first biosimilar monoclonal antibody in 2012. In 2014, Celltrion achieved another global first, and obtained approval for a biosimilar oncology monoclonal antibody. Celltrion has since introduced other biosimilars for the treatment of various types of cancer and autoimmune diseases in Europe, Korea, and Canada. Since its founding, Celltrion has devoted itself to improving patient access to advanced and novel therapeutics for the treatment of life-altering and life-threatening diseases. Celltrion has invested in major cell lines and core technologies to develop biosimilars and novel drugs and vaccines.

31. In 2013, Celltrion began development of Truxima®, a biosimilar version of Genentech's Rituxan®. Celltrion has devoted significant time, effort, and substantial monetary resources to the development of Truxima®. With its deep experience in biologics development and manufacturing, Celltrion designed the manufacturing process and process controls that have been and will be used to make Truxima®, including, among other things, developing the cell culture, harvest, and numerous purification steps to manufacture and purify the Truxima® antibody. Celltrion also conducted numerous clinical studies in which it successfully tested Truxima® in humans. In the end, Celltrion generated comprehensive analytical, pharmacokinetic,

pharmacodynamics, and clinical data that was submitted to the FDA as part of the FDA-approval process.

32. In 2016, Celltrion Inc., Celltrion Healthcare, and TPIG entered into an exclusive partnership to commercialize Truxima® in the United States. Teva USA will market Truxima® in the United States. Teva is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions used by millions of patients every day. Teva has a portfolio of more than 1,800 molecules and has a world-leading position in innovative treatments. Teva is also a leader in biologic and biosimilar development.

Congress Enacts Legislation Creating a Regulatory Pathway for Biosimilar Biological Products

33. With the passage of the BPCIA, Congress created a new pathway for FDA review and approval of "biosimilar" biological products, as well as new mechanisms to resolve patent disputes that may arise with respect to such products.

34. "The BPCIA governs a type of drug called a biosimilar, which is a biologic product that is highly similar to a biologic product that has already been approved by the Food and Drug Administration (FDA)." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017).

35. The BPCIA sets forth an abbreviated pathway for FDA approval of biosimilars. 42 U.S.C. § 262(k). To obtain approval through the BPCIA's abbreviated process, an applicant must show that its biosimilar product is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the two products in terms of "safety, purity, and potency." 42 U.S.C. § 262(k)(2). Under the BPCIA, an applicant may not submit an application until 4 years after the reference product is first licensed, and the FDA may not license a biosimilar until 12 years after the reference product is first licensed. 42 U.S.C. § 262(k)(7).

36. The reference product sponsor (also known as an "RPS") may have patents relating to the biological product, as well as therapeutic uses for and/or processes used to manufacture the biological product, that it believes may be relevant to the biosimilar product. In recognition that there may be patent disputes between the RPS and the biosimilar applicant, "[t]he BPCIA sets forth

a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of [patent] infringement." *Sandoz*, 137 S. Ct. at 1671 (citing 42 U.S.C. § 262(*l*)).

37. The BPCIA describes a process whereby the RPS and the biosimilar applicant may exchange information in advance of an action for patent infringement. *First*, the process begins when the applicant provides "a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). In addition, the applicant "may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor." 42 U.S.C. § 262(*l*)(2)(B). *Second*, the BPCIA states that the RPS shall provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor . . . if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(A). *Third*, the BPCIA requires the applicant who chooses to exchange information in advance of an action for patent infringement to provide a "detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(B)(ii)(I). Alternatively, the applicant can provide "a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires." 42 U.S.C. § 262(*l*)(3)(B)(ii)(II). *Last*, the BPCIA states that the RPS "shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I)." 42 U.S.C. § 262(*l*)(3)(C).

38. Following the information exchange, the BPCIA requires the reference product sponsor and the applicant to engage in "good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6) [of the statute]." 42 U.S.C. § 262(*l*)(4). If the subsection (k) application and RPS disagree over which patents should be litigated, the statute provides for a mechanism of further exchanges to determine which patent(s) will be the subject of a paragraph (6) patent litigation. 42 U.S.C. § 262(*l*)(4)(B)-(5).

39. Paragraph (*l*)(8) of the BPCIA states that "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). Once the applicant's notice of commercial marketing is received by the reference product sponsor, any limitation under the BPCIA on bringing an action under section 2201 of title 28 for a declaration of rights concerning patent infringement, validity and/or enforceability is lifted. 42 U.S.C. § 262(*l*)(9). "If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the [RPS] nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B)." 42 U.S.C. § 262(*l*)(9)(A).

40. Any manufacture and use of CT-P10 by any of Plaintiffs prior to commercial marketing was and is solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

The Parties' Exchanges Following the Filing of Celltrion's Subsection (k) Application for Approval of The Biosimilar Product

41. According to the FDA's "Purple Book," Genentech's Rituxan® was first approved on November 26, 1997.

42. On April 28, 2017, Celltrion Inc. submitted its Abbreviated Biologics License Application ("aBLA") for Truxima® pursuant to 42 U.S.C. § 262(k). Celltrion Inc.'s aBLA was filed after the expiration of the 4-year and 12-year statutory periods provided by 42 U.S.C. § 262(k)(7). Celltrion Inc. received notification from the FDA that its aBLA had been accepted for review on June 27, 2017.

43. On June 30, 2017, prior to the deadline under 42 U.S.C. § 262(*l*)(2)(A) for Celltrion Inc. to produce its aBLA, Genentech wrote a letter to Celltrion Inc. requesting that Celltrion Inc. produce vaguely defined information relating to the processes used in the production of Truxima® regardless of whether such information was included in Celltrion Inc.'s aBLA.

44. On July 17, 2017, Celltrion Inc. timely sent to Genentech its disclosure pursuant to 42 U.S.C. § 262(*l*)(2)(A), including the aBLA for Truxima® and other detailed information regarding the manufacturing processes used to make Truxima®. Specifically, Celltrion Inc. produced its aBLA and upstream and downstream manufacturing reports describing in detail the manufacturing process for Truxima®. Celltrion Inc.'s production of more than 440,000 pages of technical details and batch records described, among other things, (i) the source, history, and generation of the cell substrate, (ii) the cell culture and harvest process, (iii) each and every purification process step, and (iv) raw materials used during the manufacture of Truxima®.

45. Celltrion Inc.'s production contained sufficiently detailed information regarding its biosimilar product and manufacturing processes, which complied with the production requirements in 42 U.S.C. § 262(*l*)(2)(A)-(B) and enabled Genentech to undertake its obligations under 42 U.S.C. § 262(*l*)(3)(A).

46. On September 14, 2017, Genentech provided Celltrion Inc. with its list of patents "pursuant to 42 U.S.C. § 262(*l*)(3)(A)" ("the (3)(A) list") that Genentech "believe[d] could reasonably be asserted against Celltrion's proposed CT-P10 product based upon a review of the product's aBLA filing." Genentech's (3)(A) list included a total of 40 patents, including all of the patents-in-suit. 42 U.S.C. § 262(*l*)(3)(A) requires a reference product sponsor or RPS to identify the patents for which the RPS "believes a claim of patent infringement could reasonably be asserted by

[the RPS] or by a patent owner that has granted an exclusive license to [the RPS] with respect to [the reference product]." 42 U.S.C. § 262(*l*)(3)(A). Therefore, by identifying a patent on its (3)(A) list, Genentech has represented that it has the right to assert the patent as the patent owner, or exclusive licensee. Genentech never stated that there were any patents for which it lacked sufficient information and therefore was unable to conduct an analysis for its (3)(A) list.

47. On November 7, 2017, Celltrion Inc. timely responded to Genentech's (3)(A) list by providing Genentech with a statement pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(II), and further providing Genentech, pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(I), with a 466-page detailed statement that describes on a claim-by-claim basis the factual and legal bases for Celltrion Inc.'s opinion that patents included on Genentech's (3)(A) list are not infringed and/or are invalid (Celltrion's "(3)(B) statement"). Celltrion Inc. annotated its non-infringement contentions with detailed citations to its aBLA and the other documents that Celltrion Inc. had produced to Genentech.

48. Despite being under no obligation to do so, throughout the summer and fall of 2017, Celltrion Inc. worked diligently to obtain, and did obtain, the right to disclose to Genentech the documents of [redacted] that were potentially relevant to Celltrion Inc.'s CT-P10 manufacturing process. Celltrion Inc. produced these documents, along with recent FDA correspondence related to Celltrion Inc.'s aBLA, with Celltrion's (3)(B) statement. Celltrion Inc.'s extraordinary efforts alleviated the need for Genentech to seek third party discovery to obtain these documents.

49. Thus, Celltrion's (3)(B) statement identifying the bases for Celltrion Inc.'s non-infringement of Genentech's (3)(A) patents cited extensively to documents that Celltrion Inc. had produced to Genentech. Therefore, contrary to any allegation by Genentech that Celltrion Inc.'s document productions pursuant to 42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(*l*)(3)(B) were deficient, Celltrion Inc. produced substantially more documentation than was required by the statute, and Genentech had in its possession all the information it needed to determine whether Celltrion Inc.'s Truxima® product would infringe Genentech's (3)(A) patents.

50. In Celltrion's (3)(B) statement, it also stated in accordance with [redacted] Therefore, Celltrion's (3)(B) statement provided detailed statements regarding non-infringement and/or invalidity for 37 of the 40 patents on Genentech's (3)(A) list.

51. On January 5, 2018, Celltrion Inc. received Genentech's alleged statement pursuant to § 262(*l*)(3)(C) (Genentech's "(3)(C) statement"). Even though the BPCIA required Genentech to provide, among other things, "on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that [each] patent [identified in Celltrion's (3)(B) statement] will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application," and a response to Celltrion's opinions concerning the validity of the listed patents, [redacted]

[redacted]

52. Genentech failed to provide a response as to these patents as required by the BPCIA. [redacted]

53. On January 11, 2018, Celltrion Inc. wrote to Genentech in response to its (3)(C) statement. Celltrion Inc. stated that, pursuant to 42 U.S.C. § 262(*l*)(4)(A), Celltrion Inc. wished to litigate all of the patents on Genentech's (3)(A) list, [redacted].

54. [redacted], Celltrion Inc. also informed Genentech that, pursuant to 42 U.S.C. § 262(l)(8)(A), Celltrion Inc. was providing notice that commercial marketing of Truxima® may begin as early as 180 days from the date of the notice.

THE PATENTS-IN-SUIT

55. U.S. Patent No. 6,331,415 (Exhibit 1), titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells For Use Therein," issued on December 18, 2001. Upon information and belief, the '415 patent is assigned to Genentech and City of Hope.

56. U.S. Patent No. 6,417,335 (Exhibit 2), titled "Protein Purification," issued on July 9, 2002. Upon information and belief the '335 patent is assigned to Genentech.

57. U.S. Patent No. 6,455,043 (Exhibit 3), titled "Combination therapies for B-cell lymphomas comprising administration of anti-CD20 antibody," issued on September 24, 2002. Upon information and belief, the '043 patent is assigned to IDEC Pharmaceuticals Corporation.

58. U.S. Patent No. 6,489,447 (Exhibit 4), titled "Protein Purification," issued on December 3, 2002. Upon information and belief, the '447 patent is assigned to Genentech.

59. U.S. Patent No. 6,586,206 (Exhibit 5), titled "Methods for Making Recombinant Proteins Using Apoptosis Inhibitors," issued on July 1, 2003. Upon information and belief, the '206 patent is assigned to Genentech.

60. U.S. Patent No. 6,610,516 (Exhibit 6), titled "Cell Culture Process," issued on August 26, 2003. Upon information and belief, the '516 patent is assigned to Genentech.

61. U.S. Patent No. 6,620,918 (Exhibit 7), titled "Separation of Polypeptide Monomers," issued on September 16, 2003. Upon information and belief, the '918 patent is assigned to Genentech.

62. U.S. Patent No. 6,716,602 (Exhibit 8), titled "Metabolic Rate Shifts in Fermentations Expressing Recombinant Proteins," issued on April 6, 2004. Upon information and belief, the '602 patent is assigned to Genentech.

63. U.S. Patent No. 7,390,660 (Exhibit 9), titled "Methods for Growing Mammalian Cells In Vitro," issued on June 24, 2008. Upon information and belief, the '660 patent is assigned to Roche, and Genentech is the exclusive licensee with the sole right to enforce the '660 patent.

64. U.S. Patent No. 7,485,704 (Exhibit 10), titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," issued on February 3, 2009. Upon information and belief, the '704 patent is assigned to Genentech.

65. U.S. Patent No. 7,682,612 (Exhibit 11), titled "Treatment of hematologic malignancies associated with circulating tumor cells using chimeric anti-CD20 antibody" issued on March 23, 2010. Upon information and belief, the '612 patent is assigned to Biogen and Genentech.

66. U.S. Patent No. 7,807,799 (Exhibit 12), titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," issued on October 5, 2010. Upon information and belief, the '799 patent is assigned to Genentech.

67. U.S. Patent No. 7,820,161 (Exhibit 13), titled "Treatment of Autoimmune Diseases," issued on October 26, 2010. Upon information and belief, the '161 patent is assigned to Biogen and Genentech.

68. U.S. Patent No. 7,923,221 (Exhibit 14), titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen," issued on April 12, 2011. Upon information and belief, the '221 patent is assigned to Genentech and City of Hope.

69. U.S. Patent No. 7,976,838 (Exhibit 15), titled "Therapy of Autoimmune Disease in a Patient with an Inadequate Response to a TNF-alpha Inhibitor," issued on July 12, 2011. Upon information and belief, the '838 patent is assigned to Genentech.

70. U.S. Patent No. 8,044,017 (Exhibit 16), titled "Protein Purification," issued on October 25, 2011. Upon information and belief, the '017 patent is assigned to Genentech.

71. U.S. Patent No. 8,206,711 (Exhibit 17), titled "Treatment of chronic lymphocytic leukemia using anti-CD20 antibodies," issued on June 26, 2012. Upon information and belief, the '711 patent is assigned to Biogen and Genentech.

72. U.S. Patent No. 8,329,172 (Exhibit 18), titled "Combination therapies for B-cell lymphomas comprising administration of anti-CD20 antibody," issued on December 11, 2012. Upon information and belief, the '172 patent is assigned to Biogen.

73. U.S. Patent No. 8,357,301 (Exhibit 19), titled "Chromatography Equipment Characterization," issued on January 22, 2013. Upon information and belief, the '301 patent is assigned to Roche. Upon information and belief, one or more of the Defendants has the entire right, interest, and title to enforce the '301 patent.

74. U.S. Patent No. 8,460,895 (Exhibit 20), titled "Method for Producing Recombinant Proteins with a Constant Content of pCO2 in the Medium," issued on June 11, 2013. Upon information and belief, the '895 patent is assigned to Roche, and Genentech is the exclusive licensee with the sole right to enforce the '895 patent.

75. U.S. Patent No. 8,512,983 (Exhibit 21), titled "Production of Proteins in Glutamine-Free Cell Culture Media," issued on August 20, 2013. Upon information and belief, Genentech is the owner of all right, title and interest in the '983 patent.

76. U.S. Patent No. 8,545,843 (Exhibit 22), titled "Treatment of Vasculitis," issued on October 1, 2013. Upon information and belief, the '843 patent is assigned to Genentech and Biogen.

77. U.S. Patent No. 8,557,244 (Exhibit 23), titled "Treatment of aggressive non-Hodgkins lymphoma with anti-CD20 antibody," issued on October 15, 2013. Upon information and belief, the '244 patent is assigned to Biogen.

78. U.S. Patent No. 8,574,869 (Exhibit 24), titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," issued on November 5, 2013. Upon information and belief, the '869 patent is assigned to Genentech.

79. U.S. Patent No. 8,633,302 (Exhibit 25), titled "Variable Tangential Flow Filtration," issued on January 21, 2014. Upon information and belief, the '302 patent is assigned to Hoffmann-La Roche, and Genentech is the exclusive licensee with the sole right to enforce the '302 patent.

80. U.S. Patent No. 8,710,196 (Exhibit 26), titled "Protein Purification," issued on April 29, 2014. Upon information and belief, the '196 patent is assigned to Genentech.

81. U.S. Patent No. 8,771,988 (Exhibit 27), titled "Protein expression from multiple nucleic acids," issued on June 24, 2008. Upon information and belief, the '988 patent is assigned to Hoffmann-La Roche, and Genentech is the exclusive licensee with the sole right to enforce the '988 patent.

82. U.S. Patent No. 8,821,873 (Exhibit 28), titled "Treatment of diffuse large-cell lymphoma with anti-CD20 antibody," issued on September 2, 2014. Upon information and belief, the '873 patent is assigned to Biogen.

83. U.S. Patent No. 8,822,655 (Exhibit 29), titled "Pre-filtration adjustment of buffer solutes," issued on September 2, 2014. Upon information and belief, the '655 patent is assigned to Hoffmann-La Roche, and Genentech is the exclusive licensee with the sole right to enforce the '655 patent.

84. U.S. Patent No. 9,047,438 (Exhibit 30), titled "Chromatography Equipment Characterization," issued on June 2, 2015. Upon information and belief, the '438 patent is assigned to Hoffmann-La Roche.

85. U.S. Patent No. 9,080,183 (Exhibit 31), titled "Promoter," issued on July 14, 2015. Upon information and belief, the '183 patent is assigned to Hoffmann-La Roche.

86. U.S. Patent No. 9,296,821 (Exhibit 32), titled "Combination therapies for B-cell lymphomas comprising administration of anti-CD20 antibodies," issued on March 29, 2016. Upon information and belief, the '821 patent is assigned to Biogen.

87. U.S. Patent No. 9,428,548 (Exhibit 33), titled "Enhanced Protein Purification through a Modified Protein A Elution," issued on August 30, 2016. Upon information and belief, the '548 patent is assigned to Genentech.

88. U.S. Patent No. 9,428,766 (Exhibit 34), titled "Protein expression from multiple nucleic acids," issued on August 30, 2016. Upon information and belief, the '766 patent is assigned to Hoffmann-La Roche Inc., and Genentech is the exclusive licensee with the sole right to enforce the '766 patent.

89. U.S. Patent No. 9,487,809 (Exhibit 35), titled "Decreasing Lactate Level and Increasing Polypeptide Production by Downregulating the Expression of Lactate Dehydrogenase and Pyruvate Dehydrogenase Kinase," issued on November 8, 2016. Upon information and belief, the '809 patent is assigned to Genentech.

90. U.S. Patent No. 9,504,744 (Exhibit 36), titled "Treatment of diffuse large-cell lymphoma with anti-CD20 antibody," issued on November 29, 2016. Upon information and belief, the '744 patent is assigned to Biogen.

91. U.S. Patent No. 9,714,293 (Exhibit 37), titled "Production of Proteins in Glutamine-Free Cell Culture Media," issued on July 25, 2017. Upon information and belief, the '293 patent is assigned to Genentech.

COUNT I

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,331,415

92. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-91 above as if fully set forth herein.

93. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion

that one or more claims of the '415 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

94. For example, Plaintiffs will not infringe one or more claims of the '415 patent under 35 U.S.C. § 271(a) because [redacted]. Plaintiffs also will not infringe one or more claims of the '415 patent under 35 U.S.C. § 271(g) because [redacted]. However, to the extent that § 271(g) applies, Plaintiffs will not infringe one or more claims under § 271(g) because [redacted]

95. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '415 patent include: [redacted] required by certain claims of the '415 patent.

96. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '415 patent.

97. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

98. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '415 patent.

COUNT II

Declaratory Judgment of Invalidity of U.S. Patent No. 6,331,415

99. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-98 above as if fully set forth herein.

100. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '415 patent are invalid.

101. Additional non-limiting examples of how one or more claims of the '415 patent are invalid include: (1) lack of enablement of the claimed "process for producing an immunoglobulin molecule," to the extent it encompasses both *in vivo* and *in vitro* assembly, because there is no disclosure in the specification of how to produce an antibody *in vivo* in a microorganism or host cell, and undue experimentation would have been required for a POSA to do so; (2) failure of written description to describe any process for the *in vivo* assembly of an antibody or antibody fragment in either a microorganism or mammalian cell; and (3) obviousness in view of prior art disclosing processes for producing proteins, including antibodies, that can include immunoglobins (with heavy and light chains) in a single host cell using a plasmid containing genes. In addition, the claims of the '415 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '415 patent.

102. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '415 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

103. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

104. Plaintiffs are entitled to a judicial declaration that one or more claims of the '415 patent are invalid.

COUNT III

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,417,335

105. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-104 above as if fully set forth herein.

106. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '335 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

107. For example, Plaintiffs will not infringe one or more claims of the '335 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '335 patent under 35 U.S.C. § 271(g) because [redacted]. However, to the extent that § 271(g) applies, Plaintiffs will not infringe one or more claims under 271(g) because [redacted]

108. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '335 patent include: [redacted]

109. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '335 patent.

110. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

111. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '335 patent.

COUNT IV

Declaratory Judgment of Invalidity of U.S. Patent No. 6,417,335

112. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-111 above as if fully set forth herein.

113. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '335 patent are invalid.

114. One or more claims of the '335 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '335 patent. Additional non-limiting examples of how one or more claims of the '335 patent are invalid include: (1) anticipation in view of the prior art disclosing each and every limitation of claim 1 of the '335 patent regarding "purifying" of "an antibody from a composition comprising the antibody and a contaminant" by "loading the composition onto a cation exchange resin" and "eluting the contaminant from the cation exchange resin"; and (2) obviousness in view of prior art disclosing the processes of claims 1 and 3-9 of the '335 patent regarding the purification of an antibody by loading that antibody onto a cation exchange resin.

115. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '335 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

116. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

117. Plaintiffs are entitled to a judicial declaration that one or more claims of the '335 patent are invalid.

COUNT V

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,455,043

118. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-117 above as if fully set forth herein.

119. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '043 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

120. Plaintiffs will neither directly infringe the '043 patent nor induce others to infringe nor contribute to infringement by others. Additional non-limiting example of how Plaintiffs will not infringe one or more claims of the '043 patent is because [redacted]

121. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '043 patent.

122. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

123. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '043 patent.

COUNT VI

Declaratory Judgment of Invalidity of U.S. Patent No. 6,455,043

124. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-123 above as if fully set forth herein.

125. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '043 patent are invalid.

126. Additional non-limiting examples of how one or more claims of the '043 patent are invalid include: (1) anticipation by prior art disclosing methods of reducing residual CD20+ tumor cells in bone marrow or stem cell tissue after myeloablative therapy by administering an amount of a non-radiolabeled anti-CD20 antibody; and (2) obviousness in view of prior art disclosing methods of reducing residual CD20+ tumor cells in bone marrow or stem cell tissue

after myeloablative therapy by administering an amount of a non-radiolabeled anti-CD20 antibody. In addition, one or more claims of the '043 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '043 patent.

127. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '043 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

128. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

129. Plaintiffs are entitled to a judicial declaration that one or more claims of the '043 patent are invalid.

COUNT VII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,489,447

130. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-129 above as if fully set forth herein.

131. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '447 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

132. For example, Plaintiffs will not infringe one or more claims of the '447 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '447 patent under 35 U.S.C. § 271(g) because [redacted]

133. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '447 patent include that [redacted]

134. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '447 patent.

135. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

136. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '447 patent.

COUNT VIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,586,206

137. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-136 above as if fully set forth herein.

138. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '206 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

139. For example, Plaintiffs will not infringe one or more claims of the '206 patent under 35 U.S.C. § 271(a) because [redacted].

140. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '206 patent include [redacted]

[redacted]

141. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '206 patent.

142. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

143. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '206 patent.

COUNT IX

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,610,516

144. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-143 above as if fully set forth herein.

145. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '516 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

146. For example, Plaintiffs will not infringe one or more claims of the '516 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '516 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

147. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '516 patent include that [redacted]

148. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '516 patent.

149. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

150. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '516 patent.

COUNT X

Declaratory Judgment of Invalidity of U.S. Patent No. 6,610,516

151. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-150 above as if fully set forth herein.

152. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '516 patent are invalid.

153. Additional non-limiting examples of how one or more claims of the '516 patent are invalid include: (1) anticipation by prior art disclosing processes for increasing the percentage of a human glycoprotein having one glycoform by producing the glycoproteins in CHO cells in the presence of about 0 to 2 mM of a butyrate salts at a temperature of about 30° C to 35° C, and inherently and/or expressly disclosing all limitations of the claim of the '516 patent; (2) obviousness in view of prior art disclosing producing human glycoproteins with increased abundance of

particular glycoforms by including butyrate salts in the media and/or controlling the temperature of the culture in the range of 30° C. to 35° C; and (3) to the extent not obvious, lack of enablement of the claimed "process for producing a human glycoprotein having multiple glycoforms" with "an increased percentage of glycoprotein molecules having one glycoform" because there is no disclosure in the specification of how to perform the claimed process to produce glycoproteins other than t-PA, and undue experimentation would have been required for a POSA to do so. In addition, one or more claims of the '516 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '516 patent.

154. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '516 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

155. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

156. Plaintiffs are entitled to a judicial declaration that one or more claims of the '516 patent are invalid.

COUNT XI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,620,918

157. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-156 above as if fully set forth herein.

158. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '918 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

159. For example, Plaintiffs will not infringe one or more claims of the '918 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '918 patent under 35

U.S.C. § 271(g) because [redacted]

160. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '918 patent include [redacted]

161. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '918 patent.

162. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

163. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '918 patent.

COUNT XII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,716,602

164. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-163 above as if fully set forth herein.

165. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '602 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

166. For example, Plaintiffs will not infringe one or more claims of the '602 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '602 patent under 35 U.S.C. § 271(g) because [redacted]

167. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '602 patent include: [redacted]

168. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '602 patent.

169. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

170. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '602 patent.

COUNT XIII

Declaratory Judgment of Invalidity of U.S. Patent No. 6,716,602

171. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-170 above as if fully set forth herein.

172. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '602 patent are invalid.

173. Additional non-limiting examples of how one or more claims of the '602 patent are invalid include: (1) lack of enablement of the claimed "method for increasing product yield of a properly folded polypeptide," to the extent it encompasses production of protein in host cells other than prokaryotic and simple eukaryotic systems, because there is no disclosure in the specification of how to practice the invention in any complex eukaryotic system such as a CHO cell; and (2) lack of written description because the specification does not describe increasing the yield of a properly folded polypeptide in any expression system other than prokaryotic and simple eukaryotic systems. In addition, one or more claims of the '602 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '602 patent.

174. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '602 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

175. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

176. Plaintiffs are entitled to a judicial declaration that one or more claims of the '602 patent are invalid.

COUNT XIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,390,660

177. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-176 above as if fully set forth herein.

178. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '660 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

179. For example, Plaintiffs will not infringe one or more claims of the '660 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '660 patent under 35 U.S.C. § 271(g) because [redacted]

180. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '660 patent include that [redacted]

181. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '660 patent.

182. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

183. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '660 patent.

COUNT XV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,485,704

184. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-183 above as if fully set forth herein.

185. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '704 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

186. For example, Plaintiffs will not infringe one or more claims of the '704 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '704 patent under 35 U.S.C. § 271(g) because [redacted]

187. An additional, non-limiting example of how Plaintiffs will not infringe one or more valid claims of the '704 patent is that [redacted]

188. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '704 patent.

189. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

190. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '704 patent.

COUNT XVI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,682,612

191. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-190 above as if fully set forth herein.

192. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '612 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

193. Plaintiffs will neither directly infringe the '612 patent nor induce others to infringe nor contribute to infringement by others. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '612 patent include: [redacted]

[redacted].

194. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '612 patent.

195. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

196. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '612 patent.

COUNT XVII

Declaratory Judgment of Invalidity of U.S. Patent No. 7,682,612

197. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-196 above as if fully set forth herein.

198. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '612 patent are invalid.

199. Non-limiting examples of how one or more claims of the '612 patent are invalid include: (1) anticipation by prior art disclosing methods of treating chronic lymphocytic leukemia patients with anti-CD20 antibody at a dosage of about 500 to about 1500 mg/m^2; and (2) obviousness in view of prior art disclosing methods of treating chronic lymphocytic leukemia with anti-CD20 antibody given repeatedly, either alone or in combination with chemotherapy. In addition, one or more claims of the '612 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '612 patent.

200. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '612 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

201. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

202. Plaintiffs are entitled to a judicial declaration that one or more claims of the '612 patent are invalid.

COUNT XVIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,807,799

203. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-202 above as if fully set forth herein.

204. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '799 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

205. For example, Plaintiffs will not infringe one or more claims of the '799 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '799 patent under 35 U.S.C. § 271(g) because [redacted]

206. An additional, non-limiting example of how Plaintiffs will not infringe one or more valid claims of the '799 patent is that [redacted]

207. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '799 patent.

208. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

209. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '799 patent.

COUNT XIX

Declaratory Judgment of Invalidity of U.S. Patent No. 7,807,799

210. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-209 above as if fully set forth herein.

211. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '799 patent are invalid.

212. For example, one or more claims of the '799 patent are invalid as anticipated or rendered obvious in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '799 patent, including prior art that disclosed carrying out the claimed methods at room temperature of 18°C to 25°C.

213. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '799 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

214. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

215. Plaintiffs are entitled to a judicial declaration that one or more claims of the '799 patent are invalid.

COUNT XX

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,820,161

216. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-215 above as if fully set forth herein.

217. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more of claims of the '161 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

218. Non-limiting examples of how Plaintiffs will not infringe one or more claims of the '161 patent includes: [redacted]

219. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '161 patent.

220. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

221. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '161 patent.

COUNT XXI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,923,221

222. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-221 above as if fully set forth herein.

223. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '221 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

224. For example, Plaintiffs will not infringe one or more claims of the '221 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '221 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

225. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '221 patent include: [redacted]

226. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '221 patent.

227. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

228. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '221 patent.

COUNT XXII

Declaratory Judgment of Invalidity of U.S. Patent No. 7,923,221

229. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-228 above as if fully set forth herein.

230. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '221 patent are invalid.

231. One or more claims of the '221 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '221 patent. Non-limiting examples of how one or more claims of the '221 patent are invalid include: (1) lack of enablement of the claimed "process for producing an immunoglobulin molecule," to the extent it encompasses both *in vivo* and *in vitro* assembly, because there is no disclosure in the specification of how to produce an antibody *in vivo* in a microorganism or host cell, and undue experimentation

would have been required for a POSA to do so; (2) failure of written description to describe any process for the *in vivo* assembly of an antibody or antibody fragment in either a microorganism or mammalian cell; and (3) obviousness in view of prior art disclosing processes for producing proteins, including antibodies, that can include immunoglobins (with heavy and light chains) in a single host cell using a plasmid containing genes. In addition, one or more claims of the '221 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '221 patent.

232. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '221 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

233. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

234. Plaintiffs are entitled to a judicial declaration that one or more claims of the '221 patent are invalid.

COUNT XXIII

Declaratory Judgment of Invalidity of U.S. Patent No. 7,976,838

235. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-234 above as if fully set forth herein.

236. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '838 patent are invalid.

237. One or more claims of the '838 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '838 patent. Non-limiting examples of how one or more claims of the '838 patent are invalid include: (1) anticipation over prior art regarding the use of rituximab at the claimed dosage to treat rheumatoid arthritis "who experience [ ] an inadequate response to a TNFα-inhibitor"; (2) obviousness in view

of prior art disclosing the use of rituximab to treat rheumatoid arthritis patients who have rheumatoid arthritis "who experience [ ] an inadequate response to a TNFα-inhibitor" and prior art disclosing the use of rituximab at various doses to treat patients who have rheumatoid arthritis.

238. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '838 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

239. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

240. Plaintiffs are entitled to a judicial declaration that one or more claims of the '838 patent are invalid.

COUNT XXIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,044,017

241. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-240 above as if fully set forth herein.

242. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '017 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

243. For example, Plaintiffs will not infringe one or more claims of the '017 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '017 patent under 35 U.S.C. § 271(g) because [redacted]

244. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '017 patent include that [redacted]

245. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '017 patent.

246. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

247. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '017 patent.

COUNT XXV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,206,711

248. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-247 above as if fully set forth herein.

249. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '711 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

250. Plaintiffs will neither directly infringe the '711 patent nor induce others to infringe nor contribute to infringement by others. Non-limiting examples of how Plaintiffs will not infringe one or more claims of the '711 patent include: [redacted]

[redacted]

251. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '711 patent.

252. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

253. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '711 patent.

COUNT XXVI

Declaratory Judgment of Invalidity of U.S. Patent No. 8,206,711

254. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-253 above as if fully set forth herein.

255. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '711 patent are invalid.

256. Non-limiting examples of how one or more claims of the '711 patent are invalid include: (1) anticipation by prior art disclosing methods of treating chronic lymphocytic leukemia patients with anti-CD20 antibody at a dosage of 500 mg/m^2, either alone or in combination with chemotherapeutic regimen; and (2) obviousness in view of prior art disclosing methods of treating chronic lymphocytic leukemia with anti-CD20 antibody at a dosage of 500 mg/m^2 given weekly, bi-weekly or monthly, either alone or in combination with chemotherapeutic regimen. In addition, one or more claims of the '711 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '711 patent.

257. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '711 patent are invalid for failure to

comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

258. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

259. Plaintiffs are entitled to a judicial declaration that one or more claims of the '711 patent are invalid.

COUNT XXVII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,329,172

260. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-259 above as if fully set forth herein.

261. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '172 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

262. Plaintiffs will neither directly infringe the '172 patent nor induce others to infringe nor contribute to infringement by others. A non-limiting example of how Plaintiffs will not infringe one or more claims of the '172 patent includes: [redacted]

263. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '172 patent.

264. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

265. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '172 patent.

COUNT XXVIII

Declaratory Judgment of Invalidity of U.S. Patent No. 8,329,172

266. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-265 above as if fully set forth herein.

267. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '172 patent are invalid.

268. Non-limiting examples of how one or more claims of the '172 patent are invalid include: (1) anticipation by prior art disclosing a method of treating low-grade B-cell non-Hodgkin's lymphoma in a patient who has responded to CVP therapy by administering rituximab maintenance therapy, comprised of four weekly 375mg/m^2 rituximab doses given every 6 months for 2 years; and (2) obviousness in view of prior art disclosing a method of treating low-grade B-cell non-Hodgkin's lymphoma in a patient who has responded to CVP (cyclophosphamide, vincristine and prednisone) therapy by administering rituximab maintenance therapy, comprised of four weekly 375mg/m^2 rituximab doses given every 6 months for 2 years. In addition, one or more claims of the '172 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '172 patent.

269. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '172 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

270. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

271. Plaintiffs are entitled to a judicial declaration that one or more claims of the '172 patent are invalid.

COUNT XXIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,357,301

272. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-271 above as if fully set forth herein.

273. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '301 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

274. For example, Plaintiffs will not infringe one or more claims of the '301 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '301 patent under 35 U.S.C. § 271(g) because [redacted]

275. Additional, non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '301 patent include because [redacted].

276. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '301 patent.

277. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

278. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '301 patent.

COUNT XXX

Declaratory Judgment of Invalidity of U.S. Patent No. 8,357,301

279. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-278 above as if fully set forth herein.

280. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '301 patent are invalid.

281. Non-limiting examples of how one or more claims of the '301 patent are invalid include because the claims of the '301 patent are directed essentially to a method of calculating using a mathematical formula, which are invalid as unpatentable subject matter under 35 U.S.C. § 101.

282. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '301 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

283. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

284. Plaintiffs are entitled to a judicial declaration that one or more claims of the '301 patent are invalid.

COUNT XXXI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,460,895

285. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-284 above as if fully set forth herein.

286. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '895 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

287. For example, Plaintiffs will not infringe one or more claims of the '895 patent under 35 U.S.C. § 271(a) because [redacted]

288. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '895 patent include: [redacted]

289. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '895 patent.

290. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

291. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '895 patent.

COUNT XXXII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,512,983

292. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-291 above as if fully set forth herein.

293. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '983 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

294. For example, Plaintiffs will not infringe one or more claims of the '983 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs will not infringe the product claim of the '983 patent (claim 25) under

35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '983 patent under 35 U.S.C. § 271(g) because [redacted]

295. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '983 patent include: [redacted]

296. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '983 patent.

297. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

298. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '983 patent.

COUNT XXXIII

Declaratory Judgment of Invalidity of U.S. Patent No. 8,512,983

299. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-298 above as if fully set forth herein.

300. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '983 patent are invalid.

301. Non-limiting examples of how one or more claims of the '983 patent are invalid include: (1) anticipation by prior art disclosing expression of therapeutic proteins in CHO cells cultured in glutamine-free media containing asparagine in the claimed range of 7.5 mmM to 15 mM and every other claim limitation; and (2) obviousness over prior art disclosing expression of therapeutic proteins in CHO cells cultured in glutamine-free media containing asparagine in the claimed range of 7.5 mmM to 15 mM, and art disclosing the production of therapeutic proteins, including anti-CD20 antibodies, in CHO cells. In addition, the claims of the '983 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '983 patent.

302. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '983 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

303. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

304. Plaintiffs are entitled to a judicial declaration that one or more claims of the '983 patent are invalid.

COUNT XXXIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,545,843

305. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-304 above as if fully set forth herein.

306. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion

that one or more claims of the '843 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

307. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '843 patent include that Plaintiffs will not treat patients and therefore will not infringe the claims directed to methods of treatment.

308. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '843 patent.

309. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

310. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '843 patent.

COUNT XXXV

Declaratory Judgment of Invalidity of U.S. Patent No. 8,545,843

311. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-310 above as if fully set forth herein.

312. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '843 patent are invalid.

313. Non-limiting examples of how one or more claims of the '843 patent are invalid include: (1) obviousness in view of prior art teachings that depletion of B-cells would be an effective mechanism for treating a type of vasculitis, that rituximab causes depletion of B-cells in humans, and that types of vasculitis were typically treated with combination therapy that included steroids, including glucocorticosteroids; (2) obviousness in view of prior art teachings that autoimmune or inflammatory diseases, including vasculitides and Wegener's granulomatosis, can be treated with administration of TNF antagonists in combination with anti-B cell antibodies, and that rituximab was an anti-B cell antibody that was used in humans; (3) obviousness in view of prior art teachings that

vasculitis was known to occur in systemic lupus erythematosus, that B cells were an ideal target for lupus therapy, and that rituximab was known to cause B-cell depletion in humans; and (4) invalidity under 35 U.S.C. § 112 for lack of written description because the '843 patent does not provide any description of the use of rituximab to treat vasculitis that would convey to a POSA that the inventors had possession of the claimed methods.

314. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '843 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

315. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

316. Plaintiffs are entitled to a judicial declaration that one or more claims of the '843 patent are invalid.

COUNT XXXVI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,557,244

317. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-316 above as if fully set forth herein.

318. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '244 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

319. Plaintiffs will neither directly infringe the '244 patent nor induce others to infringe nor contribute to infringement by others. A non-limiting example of how Plaintiffs will not infringe one or more valid claims of the '244 patent includes: [redacted]

320. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '244 patent.

321. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

322. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '244 patent.

COUNT XXXVII

Declaratory Judgment of Invalidity of U.S. Patent No. 8,557,244

323. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-322 above as if fully set forth herein.

324. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '244 patent are invalid.

325. A non-limiting example of how one or more claims of the '244 patent are invalid includes: obviousness in view of prior art disclosing methods of treating diffuse large cell lymphoma patients who are over the age of 60 and have bulky disease with unlabeled anti-CD20 antibody and CHOP chemotherapy. In addition, one or more of the claims of the '244 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '244 patent.

326. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '244 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

327. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

328. Plaintiffs are entitled to a judicial declaration that one or more claims of the '244 patent are invalid.

COUNT XXXVIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,574,869

329. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-328 above as if fully set forth herein.

330. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '869 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

331. For example, Plaintiffs will not infringe one or more claims of the '869 patent under 35 U.S.C. § 271(a) because [redacted]. Plaintiffs also will not infringe one or more claims of the '869 patent under 35 U.S.C. § 271(g) because [redacted]

332. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '869 patent include: [redacted]

333. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '869 patent.

334. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

335. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '869 patent.

COUNT XXXIX

Declaratory Judgment of Invalidity of U.S. Patent No. 8,574,869

336. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-335 above as if fully set forth herein.

337. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '869 patent is invalid.

338. Non-limiting examples of how one or more claims of the '869 patent are invalid include: (1) lack of written description for the claim term "following fermentation, sparging the pre-harvest or harvested culture fluid" as the patent is silent concerning any air sparging of a pre-harvest cell culture fluid, let alone a post-fermentation, pre-harvest solution; and (2) obviousness in view of prior art disclosing processes for methods of preventing the reduction of disulfide bonds via air sparging. In addition, one or more claims of the '869 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '869 patent.

339. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '869 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

340. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

341. Plaintiffs are entitled to a judicial declaration that one or more claims of the '869 patent are invalid.

COUNT XL

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,633,302

342. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-341 above as if fully set forth herein.

343. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '302 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

344. For example, Plaintiffs will not infringe one or more claims of the '302 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '302 patent under 35 U.S.C. § 271(g) because [redacted]

345. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '302 patent include that [redacted]

346. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '302 patent.

347. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

348. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '302 patent.

COUNT XLI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,710,196

349. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-348 above as if fully set forth herein.

350. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '196 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

351. Plaintiffs will not infringe one or more claims of the '196 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '196 patent under 35 U.S.C. § 271(g) because [redacted]

352. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '196 patent include: [redacted]

353. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '196 patent.

354. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

355. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '196 patent.

COUNT XLII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,771,988

356. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-355 above as if fully set forth herein.

357. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '988 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

358. For example, Plaintiffs will not infringe one or more claims of the '988 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '988 patent under 35 U.S.C. § 271(g) because [redacted]

359. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '988 patent include [redacted]

360. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '988 patent.

361. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

362. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '988 patent.

COUNT XLIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,821,873

363. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-362 above as if fully set forth herein.

364. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '873 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

365. Plaintiffs will neither directly infringe the '873 patent nor induce others to infringe nor contribute to infringement by others. Non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '873 patent include: [redacted]

366. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '873 patent.

367. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

368. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '873 patent.

COUNT XLIV

Declaratory Judgment of Invalidity of U.S. Patent No. 8,821,873

369. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-368 above as if fully set forth herein.

370. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '873 patent are invalid.

371. An additional non-limiting example of how one or more claims of the '873 patent are invalid includes: obviousness in view of prior art disclosing methods of treating diffuse large cell lymphoma patients over the age of 60 with anti-CD20 antibody in combination with CHOP chemotherapy and/or stem cell transplantation regimen. In addition, one or more claims of the '873 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '873 patent.

372. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '873 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

373. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

374. Plaintiffs are entitled to a judicial declaration that one or more claims of the '873 patent are invalid.

COUNT XLV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,822,655

375. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-374 above as if fully set forth herein.

376. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '655 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

377. For example, Plaintiffs will not infringe one or more claims of the '655 patent under 35 U.S.C. § 271(a) because [redacted]

[redacted]. Plaintiffs also will not infringe one or more claims of the '655 patent under 35 U.S.C. § 271(g) because [redacted]

378. An additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '655 patent include that [redacted]

379. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '655 patent.

380. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

381. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '655 patent.

COUNT XLVI

Declaratory Judgment of Invalidity of U.S. Patent No. 8,822,655

382. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-381 above as if fully set forth herein.

383. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '655 patent are invalid.

384. Additional non-limiting examples of how one or more claims of the '655 patent are invalid include a failure to claim patentable subject matter as each claim of the '655 patent is directed towards an abstract idea, including the use of two equations to determine how to adjust a

"first concentration" of buffer substance to arrive at "a second concentration" in order to allegedly achieve a more consistent preparation of immunoglobulin after concentration by tangential flow filtration.

385. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '655 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

386. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

387. Plaintiffs are entitled to a judicial declaration that one or more claims of the '655 patent are invalid.

COUNT XLVII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,047,438

388. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-387 above as if fully set forth herein.

389. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '438 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

390. For example, Plaintiffs will not infringe one or more claims of the '438 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '438 patent under 35 U.S.C. § 271(g) because [redacted]

391. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '438 patent include [redacted]

[redacted]

392. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '438 patent.

393. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

394. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '438 patent.

COUNT XLVIII

Declaratory Judgment of Invalidity of U.S. Patent No. 9,047,438

395. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-394 above as if fully set forth herein.

396. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '438 patent are invalid.

397. Additional non-limiting examples of how one or more claims of the '438 patent are invalid include because the claims of the '438 patent are directed essentially to a method of calculating using a mathematical formula, which are invalid as unpatentable subject matter under 35 U.S.C. § 101.

398. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '438 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

399. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

400. Plaintiffs are entitled to a judicial declaration that one or more claims of the '438 patent are invalid.

COUNT XLIX

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,080,183

401. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-400 above as if fully set forth herein.

402. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '183 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

403. A non-limiting example of how Plaintiffs will not infringe one or more valid claims of the '183 patent includes: [redacted]

404. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '183 patent.

405. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

406. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '183 patent.

COUNT L

Declaratory Judgment of Invalidity of U.S. Patent No. 9,080,183

407. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-406 above as if fully set forth herein.

408. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '183 patent are invalid.

409. Additional non-limiting examples of how one or more claims of the '183 patent are invalid include: (1) obviousness in view of prior art disclosing methods of expressing a heterologous polypeptide by transfecting mammalian host cells with a plasmid containing a selectable resistance marker and a gene of interest in separate cassettes, wherein the plasmid comprises SEQ ID. NO: 04 described in the '183 patent and a nucleic acid sequence encoding a selectable marker selected from the group consisting of hygromycin phosphotransferase, neomycin and G418 aminoglycoside phosphotransferase, dLNGFR and GFP; and (2) obviousness in view of prior art disclosing methods of expressing a heterologous polypeptide by transfecting mammalian host cells with a plasmid containing a gene of interest and SEQ ID. NO: 04 described in the '183 patent. In addition, one or more claims of the '183 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '183 patent.

410. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '183 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

411. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

412. Plaintiffs are entitled to a judicial declaration that one or more claims of the '183 patent are invalid.

COUNT LI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,296,821

413. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-412 above as if fully set forth herein.

414. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '821 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

415. Plaintiffs will neither directly infringe the '821 patent nor induce others to infringe nor contribute to infringement by others. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '821 patent include: [redacted].

416. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '821 patent.

417. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

418. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '821 patent.

COUNT LII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,428,548

419. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-418 above as if fully set forth herein.

420. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '548 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

421. For example, Plaintiffs will not infringe one or more claims of the '548 patent under 35 U.S.C. § 271(a) because [redacted]

[redacted] Plaintiffs also will not infringe one or more claims of the '548 patent under 35 U.S.C. § 271(g) because [redacted]

422. An additional non-limiting example of how Plaintiffs will not infringe one or more valid claims of the '548 patent include that [redacted]

423. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '548 patent.

424. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

425. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '548 patent.

COUNT LIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,428,766

426. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-425 above as if fully set forth herein.

427. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion

that one or more claims of the '766 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

428. For example, Plaintiffs will not infringe one or more claims of the '766 patent under 35 U.S.C. § 271(a) because [redacted]

429. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '766 patent include [redacted]

430. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '766 patent.

431. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

432. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '766 patent.

COUNT LIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,487,809

433. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-432 above as if fully set forth herein.

434. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '809 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

435. For example, Plaintiffs will not infringe one or more claims of the '809 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '809 patent under 35 U.S.C. § 271(g) because [redacted]

436. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '809 patent include that [redacted]

437. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '809 patent.

438. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

439. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '809 patent.

COUNT LV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,504,744

440. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-439 above as if fully set forth herein.

441. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion

that one or more claims of the '744 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

442. Plaintiffs will neither directly infringe the '744 patent nor induce others to infringe nor contribute to infringement by others. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '744 patent include: [redacted]

443. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '744 patent.

444. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

445. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '744 patent.

COUNT LVI

Declaratory Judgment of Invalidity of U.S. Patent No. 9,504,744

446. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-445 above as if fully set forth herein.

447. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '744 patent are invalid.

448. Additional non-limiting examples of how one or more claims of the '744 patent are invalid include: (1) obviousness in view of prior art disclosing methods of treating diffuse large cell lymphoma patients over the age of 60 with anti-CD20 antibody and CHOP chemotherapy, wherein anti-CD0 antibody is administered in combination with transplantation regimen; and (2) obviousness

in view of prior art disclosing methods of treating diffuse large cell lymphoma patients over the age of 60 with anti-CD20 antibody and CHOP chemotherapy, wherein both are administered either concurrently or on day 1 of each chemotherapy cycle. In addition, one or more claims of the '744 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '744 patent.

449. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether one or more claims of the '744 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

450. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

451. Plaintiffs are entitled to a judicial declaration that one or more claims of the '744 patent are invalid.

COUNT LVII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,714,293

452. Plaintiffs restate and incorporate by reference the allegations in paragraphs 1-451 above as if fully set forth herein.

453. On November 7, 2017, Celltrion provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Celltrion's opinion that one or more claims of the '293 patent will not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of CT-P10.

454. For example, Plaintiffs will not infringe one or more claims of the '293 patent under 35 U.S.C. § 271(a) because [redacted] Plaintiffs also will not infringe one or more claims of the '293 patent under 35 U.S.C. § 271(g) because [redacted]

[redacted]

455. Additional non-limiting examples of how Plaintiffs will not infringe one or more valid claims of the '293 patent include: [redacted]

456. There is a real, substantial, and justiciable controversy between Plaintiffs and Defendants concerning whether Plaintiffs will infringe any valid and enforceable claim of the '293 patent.

457. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

458. Plaintiffs are entitled to a judicial declaration that Plaintiffs have not and will not infringe, directly or indirectly, any valid and enforceable claim of the '293 patent.

PRAYER FOR RELIEF

WHEREFORE, Celltrion and Teva respectfully request that this Court enter judgment in their favor against Genentech, Biogen, Roche, and City of Hope and grant the following relief:

A. Declare that Plaintiffs have not, do not, and will not infringe any valid claim of U.S. Patent Nos. 6,331,415; 6,417,335; 6,455,043; 6,489,447; 6,586,206; 6,610,516; 6,620,918; 6,716,602; 7,390,660; 7,485,704; 7,682,612; 7,807,799; 7,820,161; 7,923,221; 8,044,017; 8,206,711; 8,329,172; 8,357,301; 8,460,895; 8,512,983; 8,545,843; 8,557,244; 8,574,869; 8,633,302; 8,710,196; 8,771,988; 8,821,873; 8,822,655; 9,047,438; 9,080,183; 9,296,821; 9,428,548; 9,428,766; 9,487,809; 9,504,744; and 9,714,293.

B. Declare that all claims of U.S. Patent Nos. 6,331,415; 6,417,335; 6,455,043; 6,610,516; 6,716,602; 7,682,612; 7,807,799; 7,923,221; 7,976,838; 8,206,711; 8,329,172;

8,357,301; 8,512,983; 8,545,843; 8,557,244; 8,574,869; 8,821,873; 8,822,655; 9,047,438; 9,080,183; and 9,504,744 are invalid.

C. Declare that this is an exceptional case in favor of Celltrion and Teva and award Celltrion and Teva their reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

D. Award Celltrion and Teva costs and expenses.

E. Award any and all such other relief as the Court determines to be just and proper, including pursuant to 28 U.S.C. § 2202.

Dated: January 11, 2018

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